

PRIMA Lab SA

Via Antonio Monti 7
6828 Balerna
Switzerland

0041 (0) 91 605 1030

info@primahometest.com
primahometest.com



PRIMA® SELF-TESTING KIT

USER MANUAL

2IN1 / 3IN1 MULTIPARAMETER DIAGNOSTIC DEVICE



CHOLESTEROL



TRIGLYCERIDES



GLUCOSE *

* ONLY FOR THE PRIMA® 3IN1.

CE
0344

REF PL300 / PL311

Made in Italy.

ENGLISH

Thank you for choosing the system PRIMA® 2in1/3in1 test for cholesterol, triglycerides, and glucose* directly to your home. This manual contains instructions on how to use step by step the instrument and its maintenance. Please read the manual carefully before performing the test.

Before carrying out the measurement we recommend that you become familiar with the instrument and procedures.

Please also read the instructions inside the boxes of different types of stripes. In case of any questions please call customer service.

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WHAT'S THE PRIMA® 2IN1/3IN1 SYSTEM FOR?

The PRIMA® 2in1/3in1 kit is a new system designed for the self-monitoring in vitro (therefore outside of the body), through the blood obtained from a finger prick, of the quantitative determination of the levels of cholesterol, triglycerides and glucose*. These parameters are often measured together as they are the key factors for the estimation of the risk of cardiovascular disease. It is designed for home use by people who want to monitor these parameters and on the basis of their levels to understand whether it is necessary to consult a doctor; and / or control the same parameters if they are too high.

Cholesterol is a waxy substance that acts as a precursor of bile acids, steroids and vitamin D. It is synthesized primarily in the liver and in the intestinal wall. In normal conditions, the liver maintains the balance between the amount of cholesterol and draw to that excreted. This balance, however, can be altered by certain diseases such as diabetes, hypertension, hypercholesterolemia and family factors also linked to an unhealthy lifestyle such as smoking, alcohol abuse and a diet rich in saturated fats in combination with a lack of physical activity. In addition, stress, oral contraceptives and pregnancy can cause elevated cholesterol levels. A high concentration of cholesterol is a major risk factor for cardiovascular events.

The Canadian Cardiovascular Society recommends the frequent measurement of blood cholesterol for men above the age of 40 and women over the age of 45, unless there are other risk factors. If, on the contrary, there are other factors, it is recommended to perform the test above 25 years of age.

The triglycerides (consisting of three molecules of fatty acids and a glycerol) are the most common form of fat that our body digests. To be absorbed these molecules are broken down in the small intestine, and then reassembled with cholesterol to form chylomicrons. Therefore in blood triglycerides are present in the form of plasma lipids related to cholesterol. While cholesterol is used to build cell membranes and some hormones, the main function of triglycerides is to store energy. All the extra calories that come from carbohydrates are converted into triglycerides and stored as fat to be burned later as a source of energy. Although it is not yet clear how, high levels of triglycerides are placed in relation to the thickening and hardening of the artery walls - atherosclerosis - which increases the risk of heart attack and heart disease. The disease is known as hypertriglyceridemia, and ignoring the high-calorie foods, can be caused by diabetes, kidney failure or genetic derivation.

The test cannot be used on infants since it has not been validated for this purpose. It does not diagnose any disease, and like any other test, the compliance with instructions is critical to obtain accurate results.

CONTENTS OF THE PACKAGING

- One digital meter,
- 5 cholesterol strips (a box of 25 strips is available to purchase separately),
- 5 triglycerides strips (a box of 25 strips is available to purchase separately),
- 10 glucose strips* (a box 50 strips* is available to purchase separately),
- Three Data-chips: one for the cholesterol, one for triglyceride and one for glucose* testing. The chip contains lot-specific information of the calibration curve for either cholesterol, triglycerides or glucose* test,
- One lancing device,
- 25 sterile lancets,
- One user manual,
- One carrying case.

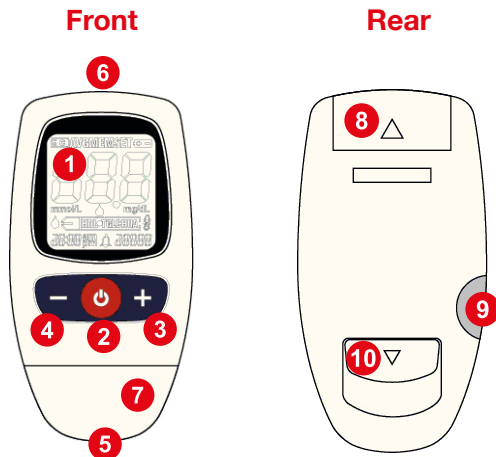
Articles non included within the packaging:

- Control solutions (available separately),
- Logbook,
- PC cable (available separately) and software.

THE DIGITAL METER

General overview of the meter

1. Display
2. Switch on button
3. '+' button
4. '-' button
5. Test strip slot
6. PC cable port
7. Cover
8. Battery space
9. Data-chip slot
10. Strip ejection button

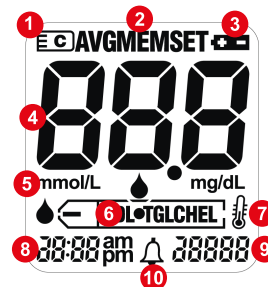


DISPLAY AND SYMBOLS

The display should be checked every time you turn on the instrument. The meter momentarily shows all the symbols that may appear in the display. Regular monitoring of all the display symbols prevents a misinterpretation of the instrument due to defects in the display.

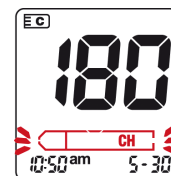
The symbols on the display have the following meanings:

1. Data-chip inserted
2. Meter mode in use
3. Battery level indicator
4. Test results and other messages
5. Units of measure
6. Parameter being tested
7. Temperature indicator
8. Time
9. Day, Month, Year
10. Beeper



Meter's modalities

The meter has three modalities:

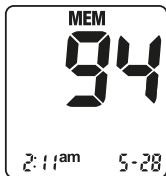


STANDBY

It's the default mode that appears every time you turn on the instrument by pressing the ON switch. The strip symbol will flash and the display will show the number of the data chip, the date and time.

MEMORY

When in Standby mode by pressing the '+' or '-' is entered in memory mode. The instrument will show the MEM symbol in the upper part of the display.



SETTINGS

Press and hold for 3 seconds the power button when the instrument is turned on. The instrument will display the SET symbol in the upper part of the display.



SETTING UP THE METER FOR THE FIRST TIME

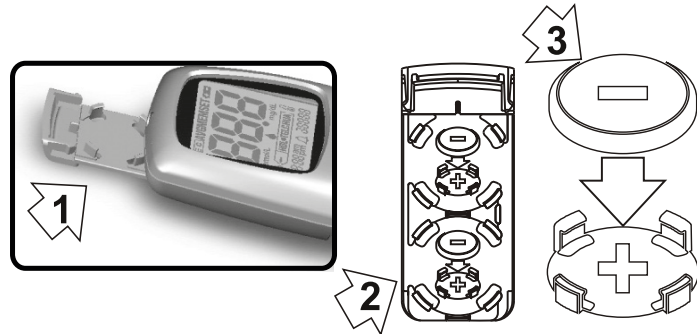
When you use the tool for the first time before turning to perform the following steps:

1. Insert the batteries.
2. Setting the time, date, and unit.
3. Insert the data-chip (it can also be done just before the measurement).

INSERTING THE BATTERIES

1. Ensure that the instrument is turned off. Open the battery cover by sliding the cover.
2. Insert two 3V lithium batteries (CR 2032) in the slot as shown, paying attention to the symbols "+" and "-" ends of the batteries. Use only 3V lithium batteries (CR 2032). Remember to always change both batteries at the same time as batteries with different capacity may interfere with the functionality of the instrument.
3. Close the battery compartment by sliding the cover until you hear a "click".
4. Turn the instrument to test the operation of the new batteries.
5. When you change the batteries, you have to insert the new ones within 1 minute to keep the same settings for date and time. If you exceed the minute you have to set new date and time. The results of the various measurements, including date and time, as well as the other settings are retained even if the batteries are not included.

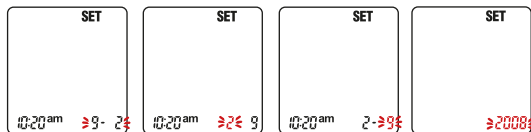
To respect the environment dispose of used batteries in accordance with the requirements of local laws of your own country. Do not throw batteries on flames as they may explode.



METER SETTINGS (SET) DAY, MONTH AND YEAR

There are 2 formats: day-month and month-day. They appear on the display in the lower right corner. To set the preferred format press and release the power button to access the SET until you see the format blink. Press the '+' or '-' to select date formats.

To select the month, day and year, press and release the power button until the signal does not blink. Press '+' or '-' buttons to set the correct month. Press power to confirm and go to the next setting. Similarly also set the date and year by pressing the '+' and '-' buttons.



TIME

There are also 2 setups for the time:

- International format of 24H;
- Anglo-American format: 12H with AM or PM.

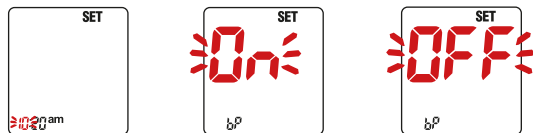
To set the preferred format press and release the power button for 3 seconds to enter the SET mode. Press power until you see the time format screen. Press '+' or '-' to choose your preferred format.



BEEPER

After setting the time, you can set the beeper and select ON or OFF. It is recommended to leave the beeper always active (default setting). If the beeper is on, you hear a beep in the following situations:

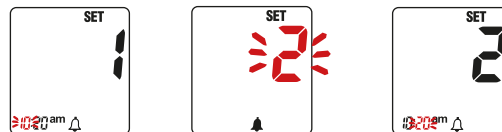
- When the instrument detects a test strip inserted;
- When the results appear on the display;



- When an error occurs.

ALARM

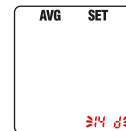
You can also set an alarm on the device in case you wish to be notified before the test. You can program up to 3 alarms. Attention, the alarm does not work when



set to 12:00 or to 0:00.

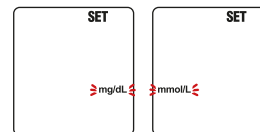
AVERAGE

You can set the device to store an average of the results of tests performed during a particular period of time. For example, an average of 14 days as shown. The principle of the setting is the same: pressing the power button with the buttons '+' and '-'.



UNITS

The device allows you to view the test results in international units such as mmol / L (used in Canada) and Anglo-American as mg / dL. You can choose the preferred unit by setting the device in SET mode and pressing the '+' and '-' buttons.



REQUIREMENTS TO PERFORM A MEASUREMENT

- Your PRIMA® Self-Testing device (2in1 or 3in1)
- Test strips for measuring the desired parameter on-chip data
- Lancing Device
- Sterile Lancet
- User's manual
- Cotton swab or gauze (not included)
- Diary where you record the results (not included).

INTRODUCTION TO TEST STRIPS AND DATA-CHIPS

The basic package of PRIMA® Self-testing Kit includes a container with 5 test strips for measuring cholesterol, one container with 5 strips for measuring triglycerides and one with 10 test strips to measure glucose*. There are also containers with 25/50 strips sold separately.

The test strips are chemically modified with enzymes. The test strip changes color by reacting with cholesterol or triglycerides present in a drop of blood and the device measures this change of color. The overall level of cholesterol or triglycerides in the blood is then shown on the display. Each new container of test strips includes a data-chip. The chip provides the device with important information about the specific properties of the respective control strips (calibration data). The chip is essential before use of the test strips. This means that you need to insert the data-chip each time you want to change parameter measurement (cholesterol, triglycerides or glucose* may to or vice versa).



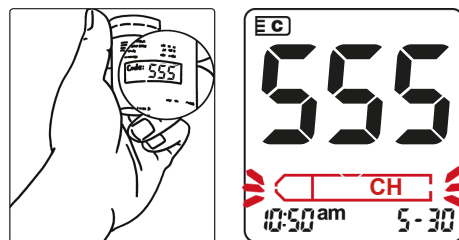
Do not forget to have the data-chip on hand, which is supplied with each container, prior to the first measurement. Every data-chip belongs to a particular lot or container. If possible, keep the container of test strips along with the date chip so it's always available.

PROGRAMMING THE DEVICE

1. Remove the Data-chip from the container.
2. Insert the chip into the appropriate slot.
3. Gently push the chip into the slot.
4. Press the button power (on/off).
5. If the meter reads the information of the chip properly, a short beep confirms the programming correct (if the beeper is enabled). The three-digit code should appear on the display. Check if this code is the same that is on the container.
6. If you have inserted the cholesterol chip, a symbol in the shape of the strip with the 'CH' characters blinking.
7. If the chip is inserted for triglycerides should see the letters 'TGL'.
8. If you inserted the glucose chip*, you should see the letters 'GLC'.



In case of problems with the programming, the device reports an error **E05** (see the Error Messages section of this manual). If an error occurs, repeat the insertion of the chip after a few seconds.



INTRODUCTION TO THE LANCET DEVICE

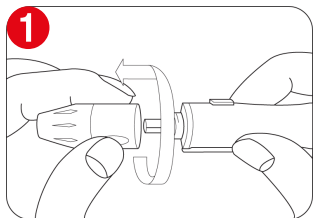
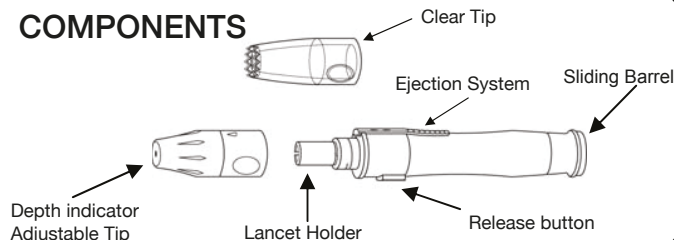
The test system includes the PRIMA® lancing device, a handy tool for collecting capillary blood samples for tests, which require one or two drops of blood. An ad-

justable tip allows 5 levels of skin penetration for individual comfort and lancets are ejected with ease and confidence.

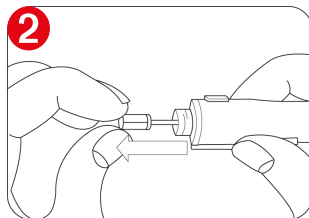
HOW TO OBTAIN A BLOOD SAMPLE

Prepare the lancing device by inserting a new sterile lancet.

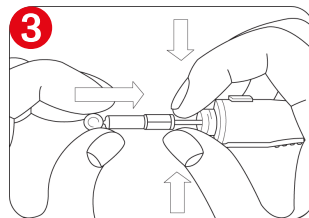
COMPONENTS



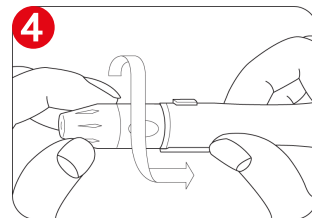
1. Unscrew the tip of the lancing device by turning it counterclockwise while holding the base.



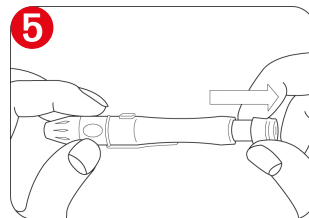
2. With two fingers, pull out the lancet carrier and hold it in place.



3. While holding the lancet carrier, insert a new sterile lancet into the bottom of lancet carrier. Twist the cap of the lancet off.



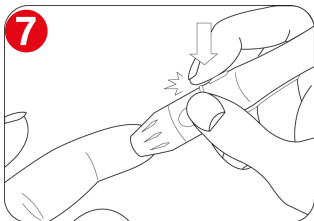
4. Put the tip of the lancing device back on and turn it clockwise.



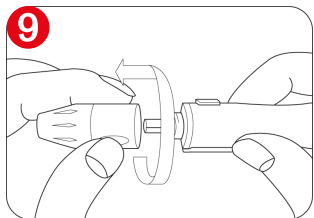
5. Hold the tip firmly in one hand then pull out the sliding barrel with the other hand. This will cock the lancing device.



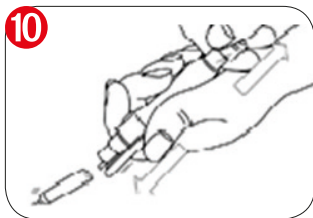
6. Wash your hands with warm water. Ensure hands are warm and dry before lancing. If needed, massage your fingertip.



7. Hold the lancing device firmly against the side of the finger, with the cap resting on the finger. The harder it is pressed the deeper is the puncture. Press the release button to prick.



9. After you finished with the measurements unscrew the tip of the lancing device by turning it counter-clock wise.



8. After lancing yourself try obtaining a hanging drop of blood. Always wipe off the first drop with a cotton ball and use the second drop for the testing.
The first drop of blood usually contains extracellular tissue fluids that may dilute your real capillary blood and cause erroneously low results.

10. Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose of the used lancet in a proper container.

PERFORMING A MEASUREMENT

- Get the test strip container for the required measurement.
- Check the expiry date of the test strips. Always use the strips before their expiry date has passed.
- Make sure that Data-chip belonging to these test strips is at hand unless the instrument has already been coded (see the section "Coding the Instrument" of this manual). **Note:** Environmental influences (e.g. air humidity and light) on the test strips may damage test strips integrity and lead to false measurements or error messages. Do not remove the test strips from the strip container until immediately before performing a test.
- Turn on the meter. Check the display before running the test. Are date and time correct? If the measured values must be stored with time information, enter the correct setting. Does battery symbol appear? If it appears, only a few more measurements can be performed. Replace batteries as soon as possible.
- If the instrument has not been coded yet, insert a respective Data-chip into designed slot. When the chip is entered correctly you will hear a beep.



- Verify if the code digit on the display corresponds to the code printed on the strip container. Now take the test strip from the test strip container. Close the container immediately after removing strip to protect the desiccants and remaining strips, otherwise, the test strips may become unusable before expiry date. Liquids must not enter the test strip container.
- Hold the test strip with thumb and index finger so that the blood sample application area is facing upwards.
- Insert the test strip into the designated strip slot. From the printing on the reverse side of the strip, the meter detects which test parameter is to be measured and which code is needed for the test strip. If the code has not been entered via data chip yet, an error message is displayed after inserting the test strip.

- Cholesterol test strips only: After inserting the strip, “F” (Female) on the left and “M” (Male) on the right will appear on the display. Press the corresponding button (“-” for “F” or “+” for “M”) to select the gender. After about two seconds, “A” (before meal) on the left or “P” (after meal) on the right will appear on the display. Press the corresponding button (“-” for “A” or “+” for “P”) to select the letter. The selected letter will remain two seconds on the display. After that, the code and the blinking drop will appear on the display, indicating that the device is ready to take the blood sample.
- Lance the outer side of the fingertip with the lancing device and a sterile lancet to obtain a large hanging drop of blood. Wipe off the first drop with the cotton ball or gauze and use the second hanging drop of blood to apply to the test strip.
- The meter displays a drop symbol on the screen window, indi-



cating that the strip is inserted and ready for the blood sample. Apply a large hanging drop of blood directly from the finger to the white sample application area of the strip. For measuring glucose*, apply a drop of blood on the end of the test strip. Let the strip aspirate the blood sample. Do not touch the application area with the finger. The drop of blood must be applied to the test strip immediately after lancing the fingertip. Blood which is applied later may lead to inaccurate result. For cholesterol and triglycerides testing it is critical to wipe away the first drop and immediately apply the second drop.

- Read and record your result. If the displayed result does not match your state of the health or seems to be unusually high or low, check the meter function using a new test strip and a control solution (not provided in the starter package). If this check confirms proper functioning of the instrument, read again the proceeding instructions of this manual. Perform another measurement using a new test strip. If the new result also seems to be not plausible, consult your doctor.
- When measurement is complete, use the ejector key on the back of the meter

to remove the used strip.

- Press power button until the instrument powers off.
- Properly dispose of the used lancets and test strip according to your local laws and guidelines.
- Clean the instrument if necessary (see the section “Care and Maintenance” of this manual).

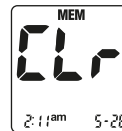
QUALITY CONTROL RECOMMENDATIONS

To ensure that meter is functioning properly, you should consider using control solutions for a function check. For each test parameter, separate control solutions are available to purchase. A function check is performed in the same way as a regular measurement except that control solutions are used instead of blood. Make a habit of carrying out a function check in the following situations:

- If you leave the test strips container opened for a long time, or if the container integrity was compromised
- If you drop the meter
- If you repeated a test and the result is still not plausible, higher or lower than expected
- When you opened a new lot of the test strip container
- When you want to check the performance of the meter and the test strip.

MEMORY

The meter is capable of storing up to 500 test results and lets you review results



in order from the most recent (1) to the oldest (500). When you insert a Data-chip into the CH meter, you can recall previous results. While in the standby, press and release ‘+’ and ‘-’ button to enter MEMORY mode. The average result will be displayed. If you press ‘+’ or ‘-’ button the memory number can be displayed. If you hold down ‘+’ or ‘-’ the meter scrolls quickly and displays memory. A result corresponding to the memory position will be shown when you release the button. To delete one of the stored results press the power button and ‘-’ button simultaneously for one second. To clear all the test results stored, continue to press power and ‘-’ buttons for five seconds.

CARE AND MAINTENANCE

A clean optical measuring system is a basic prerequisite for obtaining accurate and precise values for cholesterol and triglycerides. Therefore, regular cleans are highly recommended.

- Always power off the meter before cleaning.
- Use ordinary lint-free cotton balls or gauze or cotton clean tissue or cloth.
- Mild soap as well as 70% alcohol or isopropanol alcohol are suitable to moisten the cotton cloth to clean plastic surfaces.
- Lift the front cover and gently clean glass surfaces of the optic with a dry gauze or cotton ball.
- Clean plastic cover support of the meter with moistened and then dry gauze or cloth.
- Do not use any disinfectant sprays or cloth/cotton balls which are dripping wet as the liquid may penetrate and damage the instrument.



ERROR MESSAGES

In certain circumstances error messages may appear on your display.

E01 error means that the instrument or ambient temperature does not fall within the acceptable range for the selected test.

Solution: move the instrument to an environment which has an appropriate temperature (18°-35°C) and wait for the meter to equilibrate before repeating measurement. Do not artificially heat or cool the meter by any means.

E02 error can imply several things. First, the test strip is compromised because of coloration of the reactive area. This might happen when a used or dirty strip is inserted or when a new strip was stored inappropriately. It can also mean that the blood sample was applied too soon, before the meter displayed flashing symbol of a blood drop.

Solution: remove and discard the used strip, open the plastic lid covering the test strip slot and clean plastic window with a slightly moistened with water gauze. Take a new test strip, insert it into the designated slot and apply a blood sample only after a blood symbol is displayed on the screen.

E03 error indicates that the strip was removed prematurely, without applying a blood sample.

Solution: power off the meter and repeat the test after a few seconds.

E04 error appears when the test strip belongs to a different lot than the container which was last coded for this parameter, or when the meter was coded for cholesterol test but a strip for triglycerides was inserted for testing.

Solution: remove the strip and repeat using a test strip matching the last code for

the test being attempted. Alternatively, re-code the instrument for the respective test strip.

E05 error indicates data-chip error.

Solution: remove the chip and re-insert properly. If the E05 error remains, call Customer care.

E06 error appears when insufficient blood sample was applied to the test strip application area.

Solution: remove the used test strip and repeat the measurement applying a large drop of blood.

E07 error indicates that the data-chip is not inserted.

Solution: Insert a data-chip for proper coding of the instrument. L0 error indicates that the result falls outside of the lower limit of the instrument sensitivity (e.g. too low values).

Solution: Perform a control function check. If control passes the check, repeat the test applying a large drop of blood and ensuring that the first drop was wiped out and only the second drop was tested. If the control check fails, your instrument is not functioning properly. Contact the Customer care.

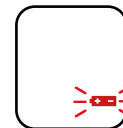
H1 error appears when the result falls outside of the higher limit of the instrument's sensitivity (e.g. too high values).

Solution: Perform a control function check. If control passes the check, repeat the test. If the repeated result is still high make a visit to your doctor. If the control check fails, your instrument is not functioning properly. Contact the Customer care.

Flashing results are indicative that the test strip is too old and may be expired. Note that flashing results are not stored in the memory.



Battery is dying and needs replacement.



PERFORMANCE SPECIFICATIONS

Operating conditions	
Relative humidity	0-90%
Temperature range for measurement	10°C-40°C
Measurement range	Cholesterol: 3.3-10.2 mmol/L (130-400 mg/dL) Triglycerides: 0.56 - 5.6 mmol/L (50-500 mg/dL) Glucose: 0.6 - 33.3 mmol/L (10 - 600 mg/dL)
Memory capacity	Up to 500 tests
Battery	2 x 3V button cells Type CR 2032
Number of measurements with new batteries	Approximately 1000
Weight	65 g (batteries included)
Dimensions	Length 97 mm Width 20.5 mm Height 49 mm
Display	LCD

WARRANTY

The meter comes with three years of limited manufacturer warranty. The warranty does not cover damages caused by improper usage and handling, accident and/or negligent care.

IMPORTANT NOTES

Always

- Operate the instrument within the acceptable temperature range.
- Place the instrument on a level surface or hold it steady in your hand.
- Make sure that all display elements are functioning during the self-test.
- Read the test strip inserts.
- Keep the meter and the test strip container clean and tidy.
- To get less variable results fast at least 10 hours before measurement.

Never

- Touch or remove the test strip during actual measurement.
- Delay starting the measurement after lancing.
- Subject the instrument to sudden movements and shakes during a measurement.
- Store the meter and test strips at extreme temperatures.
- Store the instrument and strips under humid or damp conditions without suitable protection.
- Failure to comply with the above notes may lead to inaccurate and false results.

ORDERING INFORMATION
primahometest.com

Article	Description	REF
Prima® Cholesterol Test Strips	25 test strips for determining blood cholesterol	PL301
Prima® Triglycerides Test Strips	25 test strips for determining blood triglycerides	PL303
Prima® Glucose* Test Strips	50 test strips for determining blood glucose	PL305
Prima® Cholesterol Control Solution	Control solution to be used with the cholesterol test strips	PL308
Prima® Triglycerides Control Solution	Control solution to be used with the triglycerides test strips	PL309
Prima® Glucose* Control Solution	Control solution to be used with the glucose test strips	PL307
Prima® 2in1 Multi-parameter Diagnostic Device	Device, 25 sterile lancets, 5 cholesterol strips, 5 triglycerides strips	PL300
Prima® 3in1 Multi-parameter Diagnostic Device**	Device, 25 sterile lancets, 5 cholesterol strips, 5 triglycerides strips, 10 glucose strips	PL311
Sterile lancets for Lancing device	50 Sterile lancets 100 Sterile lancets	PL313 PL314

PRODUCT LIMITATIONS

Please read the instructions of use for the test strips and control solutions for detailed information on product data and the respective limits of the test.









* PRIMA Glucose test strips with the blue data-chip and PRIMA Glucose Control Solutions are only compatible with PRIMA® 3in1 Self-Testing Kit and are not included in the 2in1 Self-Testing Kit.

**The PRIMA 3in1 Self-Testing Kit cannot be sold in the USA.

Distributed by:
PRIMA Lab SA
Via Antonio Monti 7
6828 Balerna - Switzerland

www.primahometest.com

Made in Italy

	<i>In vitro diagnostic medical device</i>		<i>Reference number</i>
	<i>Read instructions before use</i>		<i>Batch code</i>
	<i>Range temperature</i>		<i>Manufacturer</i>
	<i>Expiry date</i>		<i>CE mark</i>
		0344	

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LOGBOOK

Write down the results you get with the PRIMA® device.